UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ROBERT KILLIAN,	)	
	)	
Plaintiff,	)	CIVIL ACTION NO. 14-10794
	)	
VS.	)	
	)	
JOHNSON & JOHNSON SERVICES, INC., JOHNSON & JOHNSON, INC., DEPUY ORTHOPAEDICS, INC.,	)	JURY TRIAL DEMANDED
	)	
Defendants.	)	

PLAINTIFF'S ORIGINAL COMPLAINT

COMES NOW the Plaintiff, ROBERT KILLIAN, by and through his undersigned attorney, and, for his complaint against the Defendants, alleges as follows:

I. PARTIES

1. Plaintiff ROBERT KILLIAN is a citizen of the State of Massachusetts and resides in Weymouth, in Norfolk County.

2. Defendant Johnson & Johnson Services, Inc. is a corporation organized and existing under the laws of the State of New Jersey. Defendant Johnson & Johnson Services, Inc. is a subsidiary of Defendant Johnson & Johnson, Inc. At all times relevant to this action, Defendant Johnson & Johnson Services, Inc. has conducted business in the State of Massachusetts, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Pursuant to CASE MANAGEMENT ORDER NO. 5, this Defendant has agreed to accept requests for waiver of service of complaints pursuant to Fed. R. Civ. P. 4(d)(1) at One Johnson & Johnson Plaza, New Brunswick, NJ 08933, ATTENTION: Legal Dept.

3. Defendant Johnson & Johnson, Inc. is a corporation organized and existing under the laws of the State of New Jersey. Defendant Johnson & Johnson, Inc. is the parent company of Defendants Johnson & Johnson Services, Inc. and DePuy Orthopaedics, Inc. At all times relevant to this action, Defendant Johnson & Johnson, Inc. has conducted business in the State of Massachusetts, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Pursuant to CASE MANAGEMENT ORDER NO. 5, this Defendant has agreed to accept requests for waiver of service of complaints pursuant to Fed. R. Civ. P. 4(d)(1) at One Johnson & Johnson Plaza, New Brunswick, NJ 08933, ATTENTION: Legal Dept.

4. Defendant DePuy Orthopaedics, Inc.is a corporation organized and existing under the laws of the State of Indiana. At all times relevant to this action, defendant DePuy Orthopaedics has conducted business in the State of Massachusetts, with its principal place of business located at 700 Orthopaedics Drive, Warsaw, IN 46581. Pursuant to CASE MANAGEMENT ORDER NO. 5, this Defendant has agreed to accept requests for waiver of service of complaints pursuant to Fed. R. Civ. P. 4(d)(1) at 700 Orthopaedic Drive, P.O. Box 988, Warsaw, IN 46581, ATTENTION: Legal Dept.

II. JURISDICTION AND VENUE

5. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a)(1). The amount in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs, and no Defendant is a citizen of the same state as Plaintiff.

6. Venue is proper in this Court under 28 U.S.C. § 1391(c) and also under per this Court's Case Management Order #1, dated June 29, 2011, permitting direct filing into this Court and for consideration for transfer into MDL No. 3:11-MD-2244-K.

III. INTRODUCTION AND SUMMARY OF ACTION

7. Plaintiff alleges on information and belief against DePuy Orthopaedics, Inc., Johnson & Johnson, Inc., and Johnson & Johnson Services, Inc. the following:

8. Defendants manufactured the Pinnacle Hip Implant Device ("Pinnacle Device"). DePuy launched the Pinnacle Acetabular Cup System in 2001. The Pinnacle Device was designed, developed, and sold for human hip joints damaged or diseased due to, among other things, fracture, osteoarthritis, rheumatoid arthritis, and vascular necrosis. The Pinnacle Device is designed to be fastened to human bone with surgical screws. The Pinnacle Device was designed and sold to provide pain relief and consistent and smooth range of motion. Defendants marketed the Pinnacle devices as having significant advantages over other hip devices and hip replacement systems. Defendants marketed and described the Pinnacle Device as "uniquely designed to meet the demands of active patients like you – and help reduce pain" and advertised it with pictures of a young woman trying on sneakers in an athletic shoe store. Defendants advertised the Pinnacle Device as superior devices featuring TruGlide technology, allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion."

9. Defendants also advertised and sold the Pinnacle Device as the best surgical option that "recreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

10. On information and belief, Plaintiff alleges that Defendants sold approximately 150,000 Pinnacle Devices. Defendants have stated in promotional materials that "99.9% of Pinnacle hip components are still in use today."

11. On information and belief, Plaintiff alleges that over 1,300 adverse reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failure or complications of the Pinnacle Devices.

12. On information and belief, Plaintiff alleges that Defendants are aware that Pinnacle Devices may result in metallosis, biologic toxicity and high failure rate. Plaintiff further alleges that the Pinnacle Devices result in unsafe release of toxic metal ions into hip implant recipients' tissue and bloodstream. Plaintiff further alleges that Defendants are aware the metal particles from Pinnacle Devices results in metallosis tissue death, bone erosion and development of tumors.

13. On information and belief, Plaintiff alleges that particulate debris from the Pinnacle Devices causes severe inflammation, severe pain, tissue and bone loss, and other related diseases.

14. Plaintiff further alleges that Defendants are aware that Pinnacle Device recipients have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

15. Plaintiff was implanted with the Pinnacle Device and has suffered substantial injuries and damage.

IV. FACTUAL ALLEGATIONS

A. The Pinnacle Device with An "Ultamet" Liner

16. The Pinnacle Device was developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), fracture, and other degenerative conditions. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The

socket portion of the hip is called acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

17. The Pinnacle Device includes four components; the metal femoral stem is inserted inside the femur bone, the metal femoral head (or ball) connects to the top of the stem and then makes contact with a liner that is attached to the interior portion of the metal acetabulum cup (socket). The acetabulum cup is comprised of titanium metal on its outer shell. A plastic, ceramic, or cobalt-chromium metal liner is then placed on the inside of the acetabulum cup. The metal femoral head rotates within the plastic, ceramic, or metal liner, depending on which liner the surgeon selects based on the patient's needs. The cobalt-chromium metal liner is branded by Defendants as the "Ultamet." The Pinnacle Device with an Ultamet liner is a "metal-on-metal" device due to the fact that both articulating surfaces - the femoral head (ball) and acetabulum liner (socket) - are comprised of cobalt-chromium metal.

B. Defendants Did Not Seek Premarket Approval From the FDA, and Thus the FDA Made No Finding That the Pinnacle Device Is Safe or Effective

18. The Pinnacle Device is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

19. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Device, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

20. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or

should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

21. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

22. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device -- is not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and only requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

23. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, the Pinnacle Device metal-on-metal total hip replacement system was certified to be sold on the basis of Defendants' claim that, under section 510(k) of the MDA, it was "substantially equivalent" to another, older metal-on-metal hip implant device that Defendants sold and implanted prior to the enactment of the MDA in 1976.

24. As such, under the 510(k) process, Defendants were able to market the Pinnacle Device with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

C. Defendants Took No Steps to Test the Pinnacle Device or They Would Have Discovered That It Leads to Metallosis and Other Complications Before Releasing it on the Market

25. Had Defendants conducted clinical trials of the Pinnacle Device before it was first released on the market in the early 2000s, they would have discovered at that time what they ultimately learned in and around 2007 -- that the Pinnacle Device results in a high percentage of patients developing metallosis, biologic toxicity and an early and high failure rate due to the release of metal particles in the patient's surrounding tissue when the cobalt-chromium metal femoral head rotates within the cobalt-chromium metal acetabular liner.

26. In other words, implantation of the Pinnacle Device results in the nearly immediate systemic release of high levels of toxic metal cobalt-chromium ions into every hip implant patient's tissue and bloodstream. This is because cobalt-chromium metal particles are released by friction from the metal femoral head rotating within the metal liner. The particles then accumulate in the patient's tissue surrounding the implant giving rise to metallosis, pseudotumors or other conditions.

27. The formation of metallosis, pseudotumors, infection and inflammation causes severe pain and discomfort, death of surrounding tissue, bone loss and lack of mobility.

28. The problems with the Pinnacle Device are similar to the issues that gave rise to Defendants' recall of the ASR XL Acetabular System. Like the a Pinnacle Device, the ASR is also prone to early failure, and causes metallosis and cobalt toxicity resulting in serious health problems and the need for revision surgery. As a result, in August 2010, Defendants, in

acknowledging the high failure rate of the ASR, recalled more than 93,000 ASR hip implants worldwide. It is anticipated that Defendants will at some point recall Pinnacle Devices for the same reasons.

29. On information and belief, Plaintiff alleges that the FDA has received more than 1,300 adverse reports regarding problems associated with or attributed to the Pinnacle Device.

30. On information and belief, Plaintiff alleges that many recipients of the Pinnacle Device are suffering from elevated levels of chromium and cobalt. Plaintiff further alleges on information and belief that Defendants are aware that certain recipients of the Pinnacle Device have significantly elevated levels or chromium and cobalt in amounts many times higher than acceptable or recommended safety levels. Notably, both the ASR XL Acetabular System and the Pinnacle Device were designed by Thomas Schmalzried.

31. A number of governmental regulatory agencies have recognized the problems that are caused by metal-on-metal implants such as the ASR and Pinnacle Device. For instance, The Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

32. Similarly, the Alaska Department of Health recently issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment

of all patients who had received these and similar metal-on-metal implants.

33. Despite the public knowledge to the contrary, Defendants' continue to misrepresent the Pinnacle Device as a high quality, safe and effective hip replacement product in their marketing and promotional materials. This is despite the fact that Defendants have known for years that the Pinnacle Device poses a danger to patients that have it implanted.

34. As a result, Defendants continue to sell the Pinnacle Device to doctors who implant them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from metallosis, pseudotumors and biologic toxicity, among other complications. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems caused by the defective device.

D. Plaintiff Killian Was Implanted with a Pinnacle Device and as a Result Has Suffered Injuries

35. On or about June 20, 2007, Plaintiff Robert Killian underwent a left total hip arthroplasty procedure. A Pinnacle Device with a metal liner was implanted in place of his left hip. Over time, the known and common problem of corrosion and friction wear is believed to have caused amounts of toxic cobalt-chromium metal debris to be released into Plaintiff’s tissue surrounding the implant.

36. In the time since the implantation of the Pinnacle Device, Plaintiff began experiencing severe pain, discomfort, and inflammation in his left joint, groin, and thigh. He also felt extreme discomfort when walking.

37. MRI results from December 2011 showed significant soft tissue changes with fluid collection in the hip joint as a result of a reaction to metal.

38. Plaintiff underwent revision surgery August 14, 2012 to remove the defective

Pinnacle Device and replaced the device's metal liner with a polyethylene liner and exchanged the femoral head. To this day, Plaintiff continues to suffer harm and pain, as more fully described below.

39. To this day, Plaintiff continues to suffer harm and pain, as more fully described below.

40. Plaintiff only recently became aware of the causal link between the injuries he has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle Device and to the failure of Defendants to properly warn him and his physicians about the Pinnacle Device's defective and faulty nature. Plaintiff was unable to make an earlier discovery of the causal link despite reasonable diligence because of Defendants' failure to properly warn him and his physicians about the Pinnacle Device's defective and faulty nature, and their failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Pinnacle Device.

41. All of the injuries and complications suffered by Plaintiff were caused by the defective design, lack of adequate warnings, construction and unreasonably dangerous character of the Pinnacle Device that was implanted in him. Had Defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the Pinnacle Device, Plaintiff would not have consented to the Pinnacle Device being used in his total hip arthroplasty, but instead would have chosen one of the other hip implant devices available on the market that did not have known defects or higher rates of failure.

42. As a direct and proximate result of Defendants' defective DePuy Pinnacle hip

implant, Plaintiff has suffered, and continues to suffer, significant harm, conscious pain and suffering, physical injury, bodily impairment, mental anguish, and emotional distress.

43. As a direct and proximate result of Defendants' defective DePuy Pinnacle hip implant, Plaintiff has incurred medical expenses and other economic harm, and will continue to incur such expenses and other economic harm in the future.

44. As a result of the Defendants' wrongful acts and omissions, Plaintiff files this suit to recover his damages, as described below.

V. CAUSES OF ACTION

A. NEGLIGENCE

45. Plaintiff adopts by reference and incorporates herein the allegations set forth above.

46. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of the Pinnacle Device into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects.

47. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of the Pinnacle Device into interstate commerce. Defendants knew or should have known that those individuals that had the device surgically implanted were at risk for suffering harmful effects from it, including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are

permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life. Additionally, Defendants knew or should have known about the harmful effects from the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

48. The negligence of Defendants, their agents, servants and employees, included but was not limited to the following acts and/or omissions:

a. Negligently designing the Pinnacle Device in a manner which was dangerous to those individuals who had the device surgically implanted;

b. Designing, manufacturing, producing, creating and promoting the Pinnacle Device without adequately, sufficiently or thoroughly testing it;

c. Not conducting a sufficient testing program to determine whether or not the Pinnacle Device was safe for use;

d. Marketing and selling the Pinnacle Device when Defendants knew or should have known that it was unsafe and unfit for use because of the dangers to its users;

e. Selling the Pinnacle Device without making proper and sufficient tests to determine the dangers to its users;

f. Negligently failing to adequately and correctly warn Plaintiff or his physicians, hospitals and healthcare providers of the dangers of the Pinnacle Device;

g. Negligently failing to recall their dangerous and defective Pinnacle Device at the earliest date that it became known that the device was, in fact, dangerous and defective;

h. Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably come in contact with, and more particularly, implant the Pinnacle Device into their patients;

i. Negligently advertising and recommending the use of the Pinnacle Device despite the fact that Defendants knew or should have known of its dangerous propensities;

j. Negligently representing that the Pinnacle Device was safe for use for its intended purpose, when, in fact, it was unsafe;

k. Negligently representing that the Pinnacle Device offered low wear and high stability, when, in fact, the opposite was true;

l. Negligently manufacturing the Pinnacle Device in a manner that was dangerous to those individuals who had it implanted;

m. Negligently producing the Pinnacle Device in a manner that was dangerous to those individuals who had it implanted;

n. Negligently assembling the Pinnacle Device in a manner, that was dangerous to those individuals who had it implanted;

o. Negligently under-reporting, underestimating and downplaying the serious dangers of the Pinnacle Device.

49. Defendants were further negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Pinnacle Device in that they:

a. Failed to use due care in designing and manufacturing the Pinnacle Device so as to avoid the risks to individuals that had the devices surgically implanted;

b. Failed to accompany their product with proper warnings;

c. Failed to accompany their product with proper instructions for use;

d. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Pinnacle Device; and

e. Were otherwise careless and negligent.

50. Despite the fact that Defendants knew or should have known that the Pinnacle Device caused harm to individuals that had the device surgically implanted, Defendants continued to market, manufacture, distribute and sell the Pinnacle Device.

51. Defendants knew or should have known that consumers, such as Plaintiff, would suffer foreseeable injury and be at increased risk of suffering an injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

52. Defendants' negligence was the proximate cause of Plaintiff's physical, mental and emotional injuries and harm, and economic loss, which he has suffered and will continue to suffer in the future.

53. By reason of the foregoing, Plaintiff experienced and will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life. The revision surgery required to fix the harm caused by the Pinnacle Device lengthened his left leg, requiring him to get a 3/8 of an inch lift in his right shoe.

54. In performing the foregoing acts and omissions, Defendants acted grossly negligent, fraudulently and with malice so as to justify an award of punitive and exemplary damages.

B. STRICT LIABILITY—FAILURE TO WARN

55. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

56. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Devices.

57. The Pinnacle Devices placed into the stream of commerce by Defendants were defective due to inadequate warnings, because Defendants knew or should have known that the Pinnacle Devices could fail early in patients and therefore give rise to physical injury, pain and suffering, debilitation and the need for a revision surgery to replace the device, with the attendant risks of complications and death from such further surgery, but Defendants failed to give consumers and physicians adequate warning of such risks. Further, the Pinnacle Devices

placed into the stream of commerce by Defendants were surgically implanted in a manner reasonably anticipated by Defendants.

58. As a direct and proximate result of Defendants' placement of the defective Pinnacle Devices into the stream of commerce, Plaintiff experienced and will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life. Plaintiff also needed a revision surgery to replace the device, which carried the attendant risks of complications and death from such further surgery.

59. In performing the foregoing acts and omissions, Defendants acted with gross negligence, fraudulently, and with malice so us to justify an award of punitive and exemplary damages.

C. STRICT LIABILITY-MANUFACTURING DEFECT

60. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

61. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Devices.

62. At all times herein mentioned, the Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was in an unsafe, defective and unreasonably dangerous condition at the time it left Defendants' possession.

63. At all times herein mentioned, the Pinnacle Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without

substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

64. The Pinnacle Device that was surgically implanted in Plaintiff was defective in its manufacture when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk that it could fail early in patients thereby giving rise to physical injury, pain and suffering, debilitation and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

65. As a direct and proximate result of Defendants' placement of the defective and unreasonably dangerous Pinnacle Devices into the stream or commerce, the Plaintiff has suffered and will continue to suffer substantial damages.

D. STRICT LIABILITY-DESIGN DEFECT

66. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

67. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the Pinnacle Device that was surgically implanted in Plaintiff.

68. The Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was in an unsafe, defective, and unreasonably dangerous condition, which was dangerous to users such as Plaintiff who had the devices surgically implanted.

69. The Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was in an unsafe, defective and unreasonably dangerous condition at the time it left Defendants' possession.

70. The Pinnacle Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

71. The Pinnacle Device's unsafe, defective, and unreasonably dangerous condition was a proximate, producing or other legal cause of injury to Plaintiff.

72. The Pinnacle Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

73. Plaintiff's injuries resulted from use of the Pinnacle Device that was both intended and reasonably foreseeable by Defendants.

74. The Pinnacle Device posed a risk of danger inherent in its design which outweighed the benefits of that design.

75. The Pinnacle Device was defective and unsafe, and Defendants knew or had reason to know that it was defective and unsafe, especially when used in the form and manner as provided by Defendants.

76. Defendants knew, or should have known, that the Pinnacle Device was in a defective condition, and was and is unreasonably dangerous and unsafe.

77. At the time of the implantation of the Pinnacle Device into the Plaintiff, the product was being used for the purposes and in a manner normally intended, namely for use as a hip replacement device.

78. Defendants, with this knowledge, voluntarily designed its Pinnacle Device in a dangerous condition for use by the public and, in particular, the Plaintiff.

79. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

80. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Plaintiff, in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

81. At all times herein mentioned, there was a safer alternative design that was both technologically and economically feasible which would have eliminated or substantially reduced the damage to the Plaintiff.

82. As a direct and proximate result of Defendants' placement of the defective Pinnacle Devices into the stream of commerce, Plaintiff experienced and will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life. Plaintiff also needed a revision surgery to replace the device, which carried the attendant risks of complications and death from such further surgery.

83. In performing the foregoing acts and omissions, Defendants acted with gross negligence, fraudulently, and with malice so as to justify an award of punitive and exemplary damages.

E. NEGLIGENT MISREPRESENTATION

84. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

85. Defendants made misrepresentations and omissions of material facts, including, but not limited to:

a. That Plaintiff's implant was fit for its intended use;

b. That Plaintiff's implant was of merchantable quality;

c. That Plaintiff's implant was safe and efficacious in the treatment of Plaintiff's medical condition;

d. That Plaintiff's implant would function as intended when necessary;

e. That Plaintiff's implant was not defective, such that it would fail to function as intended; and

f. That Plaintiff's implant was not unreasonably dangerous.

86. These representations and omissions were false and misleading at the time they were made.

87. Defendants negligently and carelessly made the foregoing misrepresentations without a basis.

88. Defendants were aware that they did not possess information on which to accurately base the foregoing representations and concealed from Plaintiff that there was no reasonable basis for making these representations.

89. When Defendants made these representations, they knew or should have known them to be false.

90. In reliance upon the misrepresentations by the Defendants, Plaintiff was induced to and did subject himself to the use of the Pinnacle Device. If Plaintiff had known of the true facts, he would not have taken such action and risk. Plaintiff's reliance on Defendants' misrepresentations and omissions was reasonable because said representations were made by individuals and entities in a position to know the true facts.

91. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff has suffered and will continue to suffer injury, expense and economic loss as previously described.

F. BREACH OF EXPRESS WARRANTY

92. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

93. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Devices.

94. Defendants expressly warranted that the Pinnacle Devices were safe and effective hip replacement systems.

95. The Pinnacle Devices placed into the stream of commerce by Defendants did not conform to these express representations because they failed early, as did Plaintiff's, thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

96. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the Pinnacle Devices, Plaintiff has suffered and will continue to suffer substantial damages.

G.BREACH OF IMPLIED WARRANTY

97. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

98. Defendants are in the business of designing, manufacturing, supplying and placing into the stream of commerce the Pinnacle Devices for consumers.

99. By placing the Pinnacle Devices into the stream of commerce, Defendants impliedly warranted that they were merchantable and fit and safe for their intended use.

100. The Pinnacle Device placed into the stream of commerce by Defendants and implanted in Plaintiff was defective and accordingly, was not fit, safe, or merchantable for its intended use.

101. The defects in the Pinnacle Device designed, manufactured, supplied and placed into the stream of commerce by Defendants were present at the time the product left Defendants' control.

102. Defendants breached the implied warranty for the Pinnacle Device because it was defective, unmerchantable, and not fit for its intended purpose.

103. Plaintiff was a foreseeable user of the Pinnacle Device designed, manufactured, supplied and placed into the stream of commerce by Defendants.

104. As a direct and proximate result of Defendants' breach of these implied warranties, Plaintiff has suffered and will continue to suffer injury, expense and economic loss as previously described, rendering Defendants liable for said damages.

VI. JURY DEMAND

Plaintiff hereby demands a trial by jury as to all claims in this action.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays as follows:

a) That process issue according to law;

b) That Defendants be duly served and cited to appear and answer herein, and that after due proceedings are had, that there be judgment in favor of Plaintiff and against Defendants for the damages set forth below, along with court costs, pre-judgment and

post-judgment interest;

1. pain and suffering (past and future);
2. wage loss (past and future);
3. loss of earnings and loss of earning capacity;
4. medical expenses (past and future);
5. loss of enjoyment of life (past and future);
6. mental anguish and distress (past and future);
7. disfigurement (past and future);
8. physical impairment (past and future);
9. loss of consortium (past and future);
10. attorney's fees;
11. Punitive or exemplary damages in such amounts as may be proven at trial; and
12. For all such other relief as to which Plaintiff may show himself justly entitled.

Respectfully Submitted,
The Plaintiff
By His Attorney,

_/s/ *Peter J. Towne*_____

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Dated: March 14, 2014